

food grade wax composition with claim 17 depending therefrom.

In the Office Action, all pending claims were rejected under 35 U.S.C. §103(a) as obvious. The Office Action states:

Claims 2-9, 12, 13, 15 and 16 are rejected under 35 U.S.C. §103(a) as being obvious over Wilder et al. (US 2703807 in view of Aria et al. (JP 406200289A), Juinichi (JP 07011285), Linden et al. (US 2662907), Fuege et al. (US 2802844), and Cheng et al. (US 5374751).

Claims 10, 11 and 14 are rejected under 35 U.S.C. §103(a) as being obvious over Wilder et al. (US 2703807 in view of Aria et al. (JP 406200289A), Juinichi (JP 07011285), Linden et al. (US 2662907), Fuege et al. (US 2802844), and Cheng et al. (US 5374751), further in view of

Claims 17 and 18 are rejected under 35 U.S.C. §103(a) as being obvious over Synosky et al. (H1241), Miguel-Colombel et al. (US 5882657), and Lake (US 3931258).

Response

Applicant traverses the rejection and respectfully requests reconsideration and withdrawal thereof.

Applicant respectfully submits that the references of record, do not teach or suggest applicant's inventive matter as a whole, as recited in the claims. Further, there is no teaching or suggestion in the cited references which would lead the ordinary artisan to modify the references, in the manner suggested by the Examiner, to derive the inventive subject matter as defined in the pending claims.

As pointed out in previous responses, the U.S. Supreme Court in *Graham v. John Deere Co.*, 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under 35 U.S.C. 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and (4) inquiring as to any objective evidence of non-obviousness.

Further, applicant respectfully traverse the rejection because all three prongs for a *prima facie* case of obviousness have not been established for each of the rejections. Specifically, all the claim limitations are not present in the cited references and one of ordinary skill in the art would have no motivation to modify the cited references into the present invention.

To establish a *prima facie* case of obviousness, the Examiner must establish: (1) that some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and (3) that the prior art references teach or suggest all the claim limitations. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *Amgen, Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a

showing of the reasons why it would be obvious to modify the references to produce the present invention. See Ex parte Clapp, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. Id. at 974.

The present inventive subject matter

The process described in the present application results in production of a wax with properties that include low color from pale yellow to white, hardness (0.12 to 1.4 mm penetration depth), low odor and bland taste. The process for preparation of the white wax from crude sugar cane wax extracted from filter cake is unique. Previously, the reported color which could be achieved by various processes for treating sugar cane wax from filter cake had been pale yellow. The present process also addresses the long term and temperature stability of the color of the wax, currently not addressed by know processes for treating sugar cane wax. With standing or heating for prolonged periods at temperatures close to the melting point of the wax, the wax will often darken in color. Processes previously used, for example bleaching techniques, are unsuitable for comestible use because of the non food-grade reagents used. The present inventive process also introduces a simple but unique method for

further separating the color and polar lipid components of the wax. This is achieved through a pitch inducement, whereby heat treatment allows the color and the polar lipid components of the wax to react to form an insoluble component, which can be removed by solvent fractionation.

The process described and claimed in the present application is a combination of physical and reaction steps which removes impurities, such as color and polar lipids, providing a wax with low, and most importantly, stable color and narrower composition with a higher alcohol content, providing a sharper melting point and hardness. These steps include:

1. fractionation of the wax using the variation in the crystallization of the various components of the wax at a specific temperature and in a particular solvent, with a lower alcohol being found to be the most desirable solvent for a wax used in a comestible. This is accomplished in steps i-iv of the process set forth in claim 2.
2. Auto-oxidation of the double bonds which are partially responsible for color (note that the color of the wax is from pigments and color precursors which may not be colored but will take on color after appropriate reaction; i.e. carotenoids are unsaturated compounds which, when cleaved, will form color irreversibly,

amino acids can react with reducing sugars to give a browning effect know as the Maillard reaction) and termination of free radical formation. This is accomplished in steps i.-iv. of the process set forth in claim 2. The process also includes the optional steps v. and vi. in claim 2:

- a. Heat treatment to induce color formation from color precursors and reaction of fatty acids and other wax components which include inorganic components to form polar lipids which forms the majority of the pitch fraction aiding in the fractionation of glycerol, phosphates, sugars and amino groups from the desired wax component; or
- b. use of adsorbent to further remove additional color and other impurities responsible for color, odor and taste from the wax.

The optional steps are claimed in various dependent claims. The combination of these steps for processing crude sugar cane wax is neither taught nor suggested by what was known before the claimed invention which addresses not only the removal of impurities, but also the storage and thermal stability of the wax, which are important for the many uses of the wax composition which results from the inventive process.

The prior art cited against the process claims 2-16

To further assist the Examiner, a detailed analysis of each of the cited references follows in which the differences between a citation and the relevant process step of the claimed invention are discussed.

The primary reference cited in the Office Action, the Wilder patent (U.S. Patent No. 2,703,807). The Wilder et al. reference does not teach about the deresination process from the hardwax as suggested by the Examiner, but rather it teaches about deodorization and decolorization of the hardwax by the auto oxidation process. The crude wax of the '807 patent, which comprises of hardwax, resin and fatty fraction (Column I, line 27-29) has been previously deresinated by other means to produce the hardwax, which has been used as the initial material in this process. (See column 2, line 2, "undesirable color and odor of the hardwax"; in Example 1, column 2, line 28-29, "employed. . .100 pounds of hardwax"; Example 2, column 2, line 68, " 100 pounds of hard fraction sugar cane wax..") Although the '807 process removes the color by auto oxidation and the odor by having oxygen gas bubbling into the system, the process does not produce a comestible wax or a wax with stable properties for the following reasons:

1. By continuously blowing only oxygenated gas into the process, the auto oxidation process is not terminated, thus leaving lipid hydroperoxides byproducts which can further oxidize other wax components with storage or heating, resulting in the alteration of the wax composition and properties. The process of the claimed invention addresses these problems by blowing non-oxygenated gas to purge the odor from the wax and by the use of an adsorbent to remove compounds responsible for odor as well as residual color and taste.

2. In the Wilder ('807) patent, sugars, amino acids, phosphates and other potential color pre-cursors are not removed in the process. The oxidation step only addresses the presence of unsaturation present in certain color pre-cursors such as carotenoids, as the source of color. The Wilder ('807) process does not address the possible browning effect from the Maillard reaction resulting from the presence of amino groups and sugars present in the wax. Impurities such as phosphates, which are part of the sugar milling, are also not removed. On the other hand, in the claimed inventive process the color precursors and other impurities are removed through: pitch inducement or heat treatment, which promotes the reaction of the fatty acids with the amino groups and sugar and so on to form polar lipids; solvent fractionation of the compound with the polar lipids or

pitch; and use of adsorbent to remove residual pigments and other impurities.

Thus, Applicant respectfully shows that the '807 patent fails to teach important limitations found in independent claim 2, namely the combination of steps which result in a vastly more stable product.

The Examiner relies on the Junuichi et al. reference (JP 07011285) for evidence of conventional steps of removing pitch wax from a crude wax wherein the steps are repeated 4 times and an oxidizing material is used.

Applicant respectfully asserts that the Junuichi et al. reference teaches the process of removing the fatty fraction from the wax by a saponification process. The fatty acid and esters in the wax are reacted with metal hydroxide to form a metal soap. The purpose of this is to render these compounds insoluble in alcohol. As such, in the process of using solvent fractionation, both the pitch and the fatty fraction now in the form of metal soap will be insoluble and can be separated from the soluble hardwax fraction.

Examiner correctly states that oxidizing material, in this case hydrogen peroxide, is used in the process. However this material is used to promote the saponification process rather than the auto-oxidation process (see last 2 sentence, paragraph

0007). The process does not address the presence of unsaturation or colour precursors in the form of amino acids and sugars and the presence of phosphates. Furthermore, the process does not address the removal of residual heavy metals added into the process. The use of strongly oxidizing agent would produce hydroperoxides by-products, which will continually oxidize and alter the properties of the wax. The final hardwax produced by the Junuichi et al. process would therefore have unstable storage properties and its application for food is questionable.

The wax produced by the novel process of the present claims, on the other hand, is very stable, as the process removes the color precursors and hydroperoxide by-products. Thus, the Junuichi et al. reference fails to teach all of the claimed process limitations and therefore does not render the claims obvious.

The process described in the Linden et al. reference (U.S. Patent No. 2,662,907) uses solvent fractionation or the differences in the solubility of the wax fraction, hardwax, fatty and pitch fraction, to separate the components. The final product in the process described in the Linden et al. reference will be the hardwax. As Applicant indicates above, the hardwax contains several components and impurities, which should be removed to improve the wax's stability, and its application for

comestible use. The presence of compounds producing color (i.e. pigments and carotenoid), color precursors (i.e. amino groups and sugars), and chemical impurities (i.e. as phosphates) which are removed in the claimed inventive process is not addressed by the Linden et. al. process.

Thus, Applicant respectfully shows that the '907 patent fails to teach all of the claimed limitations found in independent claim 2, namely the combination of steps which result in a vastly more stable product.

The Examiner relies on the Fuege et al. reference (U.S. Patent No. 2,802,844) as evidence of the conventionality of purifying wax from a crude wax (rice bran wax) wherein the impurities are removed from the wax by repeating crystallization steps using iso-propanol and the wax is oxidized to remove the color.

Applicant respectfully asserts that the Fuege et al. process also uses solvent fractionation to separate the crude wax component with the hardwax as the final product of this step. The process is then followed by chemical bleaching or oxidation to remove color. The use of chemical oxidation will have a different effect than auto oxidation, which is used in the claimed inventive process. Chemical oxidation leads to reactions which will rupture double bonds and will alter the properties of

the wax. Further, the effect of the use of a strong oxidizing agent is difficult to control and will not be specific. Thus, various oxidized products will form. Wilder et al. ('807 patent suggests the effect of chemical bleaching on the wax in column 1, line 75-77. " bleaching has demonstrated a deteriorating effect on the wax. reducing the molecular structure so that the wax is soft and tacky ..". Applicant notes that although Feuge et al. consistently pointed out in samples 1 to 7 the effect of solvent fractionation on the hardwax (i.e. wax is not tacky), they are silent on the effect of chemical bleaching to the final wax (see sample 8).

Removal of various impurities, which can have significant effect on the application of wax for comestible use, were not considered. This includes: 1) chromium trioxide and sulfuric acid; 2) amino acids, sugars, phosphates and other inorganic impurities; 3) residual hydroperoxide intermediate products; and 4) odor and taste. The Fuge et al. process does not produce wax with similar properties to wax produced through the claimed inventive process and will not have comestible application.

Fuge et al. has been relied on as evidence of conventionality of removing spent bleaching agents (comprising peroxides). It should be noted that the hydrogen peroxide removed in this process is a chemical reagent considered as a

strong oxidizing reagent and its decomposition is catalyzed by the presence of heavy metals, which in Fuege et al. is present as chromium trioxide. On its own, hydrogen peroxide is quite unstable particularly in the presence of heavy metals. Once decomposed it can oxidize anything that is combustible such as the wax. Additionally, hydrogen peroxide is also corrosive. (Material Safety Data Sheet of Hydrogen Peroxide). Thus, its removal is necessary for safe storage and application of the wax and to prevent decomposition of the wax. The lipid hydrogen peroxide which are removed by bubbling inert gas in the claimed process are intermediate oxidation products which can further oxidize the wax to produce undesirable by-products such as odor and taste as suggested by Cheng et al. (discussed below). These compounds do not have the safety implications of hydrogen peroxide, but they can have an impact on the food application of the wax as further oxidation can lead to rancidity.

Thus, for the reasons set forth above, Applicant respectfully shows that the Fuege et al. reference fails to teach all of the limitations found in independent claim 2.

Next, the Examiner relies on Cheng et al. (U.S. Patent No. 5374751) as evidence including a final oil process step (i.e. after oxidation) to remove excess peroxides using an inert gas such as nitrogen, while heating the oil.

The Cheng et al. process utilizes inert gas to strip volatile components which can include peroxides products and fatty acids. However, Applicant respectfully submits that the process as described by Cheng et al. does not involve oxidation followed by stripping of residual peroxides, as suggested by the Examiner. In fact, refining of edible oil excludes the exposure of the oil to oxygen during processing (U.S. Patent No. 4,089,880, May 16 1978), as it would cause the oil to become rancid and thus inapplicable for comestible use. Bleaching of edible oil is often conducted by heating the oil with steam or by using activated clay (clay bleaching). The peroxides removed are products of long-term storage and/or with exposure to oxygen. Cheng et al. suggests that oil which can be subjected to deodorization include oil or fat material which has been degraded due to passage of time and/or to exposure to oxygen (Column 5, lines 45 and 46). Oxidation, however, is not part of the processing of edible oil, but, rather, oxidation is something which is unavoidable if the oil contains components like fatty acids, which can oxidize.

In the claimed inventive process, components which will preferentially oxidize are solvent fractionated (fatty acids) or auto-oxidized with oxygen. Intermediate products like lipid

peroxides are removed to reduce any possible further oxidation of the wax with storage or further processing.

Thus, for the reasons set forth above, Applicant respectfully shows that the Cheng et al. reference fails to teach all of the limitations found in independent claim 2.

In the Arai et al. reference (JP 406200289A) the application of an adsorbent to reduce the color and odor in crude wax was suggested by the Examiner to extend to the use of activated carbon in reducing color and odor in the process proposed. The use of activated carbon does not necessarily remove color from waxes as suggested by Fuege et al. (column, line 29-31 "Unobviously, the use of about 10% of activated clay and carbon has little effect on the colour of such waxes").

Furthermore, the activated carbon can in some instance remove colour, for example some pigments. Color precursors (i.e. unsaturated compounds, sugars and amino acids which could participate in the Maillard reaction), fatty acids, phosphates and other inorganics active in the formation of polar lipids are much more difficult to remove by the use of adsorbents because each of these components will have different sizes and adsorption properties. Additionally, since these are color precursors their effect will not be obvious until their reactions are initiated. The use of an adsorbent to reduce the color and odor

of wax as taught by Arai et al. has a temporary effect. In order to have a permanent effect, the above impurities must be allowed to initiate and then the products removed, as claimed in the claimed inventive process.

Finally, there is absolutely no suggestion in Arai et al. of the repetition of either Processes I or II. The process disclosed in Arai et al. is limited solely to Process I, followed by Process II, followed by Process III. Contrary to the Examiner's assertion, Arai does not teach the conventionality of repeating steps (i) to (iii) of claim 2.

The Examiner states in the Office Action that the Hilfman reference teaches the use of an inert gas, including nitrogen as recited in pending claims 10 and 11 in combination with a cobalt, manganese, or iron catalyst as recited in pending claim 14 to remove undesirable impurities at a temperature of 93° to 140°C. Applicant respectfully submits that Hilfman uses a hydrogenation process to remove aromatic from a paraffinic stock. Hilfman does not teach: 1) the use of an inert gas and catalyst to remove undesirable impurities and 2) the reactions are conducted between 93° to 140°C, as the Examiner implies. Hilfman, in column 1 line 6, Column 2, line 23, and Column 2, line 37 implies the use of hydrogen in the reaction, which is conducted at temperatures between 200 to 500°C (see Column 2, line 54). Additionally, the

reaction is carried out at pressure of 1000 to 2000 psi. In column 2, line 59-62, Hilfman indicates that the superatmospheric pressure is achieved by addition of inert gas with hydrogen. As such nitrogen is not used in the system to remove the aromatic impurities but rather to boost the pressure in the system to enable the hydrogenation reaction to proceed. The use of inert gas in the Hilfman process is conducted for reasons which are different those of the claimed inventive process.

Thus, for the reasons set forth above, Applicant respectfully shows that the Cheng et al. reference fails to teach all of the limitations found in independent claim 2.

Regarding claim 16, the Examiner claims that reheating the oxidized sample in isopropanol is obvious to reduce the color, as solvent extraction has been used by Junuichi et al. Junuichi et al. uses solvent fractionation to remove fatty acid soaps and pitch. Wilder et al. (column 1, line 37) suggests that pitch has a dark color," the wax so treated has not been first properly deresinated the black gummy resins impair color change" (column I line 67-68). Linden et al. has also referred to pitch in column I line 21 "resinous fraction is a black pitch". These would therefore imply that removal of the pitch, the main immediate colour-containing component, by solvent fractionation would reduce the color of the remaining wax. There is no implications

from these references that suggest the solvent fractionation is used to reduce colour but rather to fractionate the crude wax into the hard, soft and resin fractions. The reheating of the oxidized material in isopropanol is conducted in the proposed process to further fractionate any pitch, which may have formed from the oxidation process. The heat treatment, also used in this claimed inventive process, is used to further induce the polar lipid formation to remove phosphates and other impurities, which makes up most of the pitch. Subsequent removal of the pitch by fractionation therefore effects the removal of these impurities from the hardwax.

**Summary of Differences between
the Claimed Inventive Process and the cited references**

The novelty of the claimed inventive process is level of impurities and stability of the wax. In this wax, the stability has been addressed by inducing the reactions like oxidation, Maillard reaction and polar lipid formation and subsequently removing the products and intermediate products which can induce further reaction. Immediate color, odor and taste are removed by fractionation, stripping and adsorption. The combination of these steps produces a unique wax product, which has not been prepared by previous processes suggested by the Examiner either individually or in combination.

Wilder et al. produces a final product of hardwax, which has been oxidized and has less odor . However since the Wilder et al process has not removed intermediate peroxide, the product wax will continue to react. Furthermore, since sugars, amino acids and phosphates are not removed, these will remain as impurities and precursors for color and pitch formation.

Junuichi et al. produces a hardwax but, rather than solvent fractionation, the process uses saponification to convert the fatty acids into insoluble soaps. The final hardwax is unrefined and will still change again because of the presence of impurities suggested above and the presence of unsaturation.

Linden et al. produces a solvent fractionated hardwax. It would be similar to the processes of deresination implied by Wilder et al. used in producing hardwax. This hardwax will still contain the same impurities and precursors as contained in the Junuichi et al. hardwax.

Fuege et al. uses a solvent fractionation followed by chemical bleaching. As suggested by Wilder et al. the chemically bleaching may address the presence of unsaturation but it does not address the presence of the precursors. The use of chemical bleaching, which is a stronger oxidation reagent, will change the molecular structure of the wax. As such, the final product will be unlike that of the claimed inventive process.

Cheng et al. uses inert gas to strip volatile components such as fatty acids and peroxide products to remove odor and color. Fatty acids in this process are not solvent fractionated as in the sugar cane wax. The peroxides are products produced with storage and or exposure to oxygen. These are impurities, which are already present in the oil. The application of inert gas to strip impurities already present in the wax will have a temporary refining effect. Sugar cane wax contains chemical components, which will oxidize and form odor and taste. As such the application of Cheng et al. process will not have the same effect as the claimed inventive process. The claimed inventive process induced the oxidation of the wax component and then removal of the intermediate products by gas stripping. Note that oxidation is avoided in the edible refining of oil. As such, oxidation then gas stripping as used in the claimed inventive process is not used in the oil refining process.

Hilfman uses hydrogenation, which was not used in the claimed inventive process. The hydrogenation of the wax in the presence of inert gas at temperatures between 250° to 500°C, will certainly not produce the wax in the claimed inventive process.

As such, the wax produced has similar composition to some of the waxes referred to by the Examiner. However the stability and

level of purification achieved is different to what has been achieved or addressed by previous processes in sugar cane wax.

Applicant respectfully submits that claim 2 is not obvious over the prior cited against the claim as there is no teaching or motivation to combine the references in an attempt to achieve the inventive subject matter of claim 2, therefore the remaining claims are not obvious because the remaining claims contain the limitations set forth in claim 2 and the prior art fails to teach those limitations.

Accordingly, Applicant respectfully submits that claimed inventive subject matter is not obvious over the cited references and respectfully requests reconsideration and withdrawal of the rejection of claims 2-16 as being obvious thereover.

The present inventive composition

Claim 18 is drawn to a food grade wax composition, the composition comprising on a weight basis: wax esters, 6.2-11%; aldehydes, 2.8-9.5%; tri-glycerides, 0-3%; alcohols, 1.8-44.5%; and free fatty acids, sterols and polar lipids, 36.8-87.2%. Claim 17 depends from claim 1 and is drawn to a comestible which includes the food grade wax composition of claim 18.

The prior art cited against the claimed inventive composition

In contrast, Synosky et al. (H1241) disclose a universal gum base concentrate which contains about 15-25 weight percent synthetic elastomer, about 40-70 weight percent synthetic elastomer plasticizer including a terpene resin, about 10-25 weight percent wax, about 1-12 weight percent softener and about 0-3 weight percent filler. Minor quantities of antioxidants and other ingredients may also be present.

Further, the Examiner asserts the secondary reference, Miguel-Columbel et al. (U.S. Patent No. 5,882,657), teaches the conventionality of using sugar cane wax in a food grade wax composition.

The Examiner also relies on Lake (U.S. Patent No. 5,882,657) as evidence of the conventional crude sugar wax composition of fatty acids, alcohols, esters and aldehydes.

The differences between the claimed inventive composition and the cited prior art

The differences between applicant's inventive subject matter and the cited references are readily apparent from their independent and distinct disclosures and claims. It appears that the rejection is predicated on the Examiner ignoring the fact that the wax composition of the present inventive subject matter of claim 18 is a unique entity, i.e., it is a composition comprising

the components recited in the claim and is not part of the more complex compositions taught by Synosky et al. The present inventive subject matter thus provides a composition that can be *per se* obtained from sugar cane wax and does not have to be constituted from individual components.

The foregoing notwithstanding, the Synosky et al. and secondary references are silent with respect to sterols, one of the components of the composition of the present inventive subject matter of claim 18 (the composition comprises 36.8-87.2% free fatty acids, sterols, and polar lipids). Thus, even when Lake or Miguel-Columbel et al. are combined with Synosky et al. the sterol component is still not taught. Thus, the combination of the references would still be lacking an essential component of the claimed inventive subject matter.

Further, as the Examiner correctly points out, Synosky et al. is silent in teaching 2.8-9.5% aldehydes. Even assuming Synosky et al. teaches the use of sugars as sweetener and reducing sugars are aldehydes, Synosky et al. does not teach the presence of aldehydes in 2.8-9.5% by weight of the composition. Neither do the secondary references of Lake or Miguel-Columbel et al. teach the presence of aldehydes in 2.8-9.5% by weight of the composition. Again, the combination of the references would still be lacking an essential component of the claimed inventive subject matter.

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Accordingly, Applicant respectfully submits that claimed inventive subject matter is not obvious over the cited references and respectfully requests reconsideration and withdrawal of the rejection of claims 17 and 18 as being obvious thereover.

CONCLUSION

In view of the foregoing, applicant respectfully requests the Examiner to reconsider and withdraw the rejection of the claims and to allow all of the claims pending in this application.

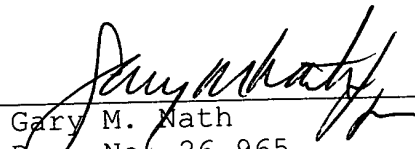
If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,

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